

REMARKS

Entry of the foregoing amendments and reconsideration of this application are respectfully requested in view of the following remarks. Claims 34-62 are pending in the application, with claims 34, 47 and 56 being the independent claims. Claims 34-62 have been added. Claims 6-14 and 21-33 have been canceled without prejudice to the subject matter contained therein. The Applicants respectfully submit that these amendments introduce no new matter. Based on the above Amendments and the following Remarks, the Applicants respectfully request that the Examiner reconsider and withdraw all outstanding rejections.

Rejections Under 35 U.S.C. § 101

Claims 1-13 and 21-33 were rejected under 35 U.S.C. § 101 as being drawn to non-statutory subject matter. Although the Applicants do not acquiesce to the Examiner's position that claims 1-13 and 21-33 are directed towards non-statutory subject matter, in an effort to advance prosecution these claims have been canceled without prejudice to the subject matter contained therein. Accordingly, the rejection of claims 1-13 and 21-33 under 35 U.S.C. § 101 is moot in view of the cancellation of these claims. Thus, the Applicants respectfully request that the rejection of claims 1-13 and 21-33 under 35 U.S.C. § 101 be withdrawn.

The Applicants further submit that new claims 34-62 are directed to subject matter eligible for patenting under 35 U.S.C. § 101, as new claims 34-62 are directed towards a prosthesis to be positioned within a body. Accordingly, the Applicants respectfully submit that the broadest reasonable interpretation of the claimed invention as a whole does not "encompasses a human being." *See e.g.,* M.P.E.P. § 2105. Moreover, although the Applicants

respectfully disagree with the Examiner's position that a rejection under 35 U.S.C. § 101 is appropriate when a claim "positively recites part of a human," (see Office Action, page 2) new claims 34-62 do not positively recite a part of a human. Thus, the claims are directed to subject matter eligible for patenting and the Applicants respectfully submit that a rejection of new claims 34-62 under 35 U.S.C. § 101 is inappropriate.

The Claims are Patentable over U.S. Patent No. 5,681,317 to Caldarise

Claims 6-13 and 21-32 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,681,317 to Caldarise ("*Caldarise*"). As discussed above, in an effort to advance prosecution these claims have been canceled without prejudice to the subject matter contained therein. Accordingly, the rejection of claims 1-13 and 21-33 under 35 U.S.C. § 102(e) is moot in view of the cancellation of these claims. Thus, the Applicants respectfully request that the rejection of claims 1-13 and 21-33 under 35 U.S.C. § 102(e) be withdrawn.

The Applicants submit that new claims 34-55 are patentable over *Caldarise* because *Caldarise* fails to disclose or suggest "each and every element as set forth" in the claims. *See e.g.*, M.P.E.P. § 2131. More particularly, *Caldarise* fails to disclose or suggest a prosthesis produced by a process including "conveying a second bone filler material into the second cavity such that the second bone filler material is substantially enclosed by the first bone filler material," as recited in new independent claims 34 and 47. Additionally, *Caldarise* fails to disclose or suggest a prosthesis including "a second layer including a second bone filler material disposed with the inner cavity such that the second layer is substantially enclosed by the first layer," as recited in new independent claim 56.

In contrast, *Caldarise* discloses a delivery device (10) that includes concentric tubes (17) and (18), each of which can contain a bone cement for delivery into a bone. *Caldarise* further discloses a plunger (14) that is movable within the concentric tubes (17) and (18) such that the bone cement contained within the concentric tubes (17) and (18) can be extruded. Thus, at best, the delivery device (10) of *Caldarise* may produce concentric regions of bone cement having an outer layer and an inner layer. The end portions of the outer layer, however, will be opened and will not substantially enclose the inner layer.

Thus, for at least this reason, the Applicants respectfully submit that new independent claims 34, 47 and 56, and the claims that depend therefrom, are patentable over *Caldarise*.

The Claims are Patentable Caldarise in view of Shastri

Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Caldarise* in view of U.S. Patent No. 5,837,752 to Shastri et al. (“*Shastri*”). As discussed above, in an effort to advance prosecution claim 14 has been canceled without prejudice to the subject matter contained therein. Accordingly, the rejection of claim 14 under 35 U.S.C. § 103(a) is moot in view of the cancellation of claim 14. Thus, the Applicants respectfully request that the rejection of claim 14 under 35 U.S.C. § 103(a) be withdrawn.

The Applicants submit that new claim 43, which includes subject matter previously presented in claim 14 is patentable over *Caldarise* in view of *Shastri*. As discussed above, *Caldarise* fails to anticipate new independent claim 34. *Shastri* fails to remedy any deficiencies in *Caldarise*. Thus, *Caldarise* in view of *Shastri* fails to disclose or suggest the recitations of new independent claim 34. For at least this reason, new independent claim 34, and its dependent claim 43, are patentable over *Caldarise* in view of *Shastri*.

Conclusion

All of the stated grounds of rejection have been properly traversed or rendered moot. The Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. The Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.


Prompt and favorable consideration of this Amendment is respectfully requested.

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Respectfully submitted,
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